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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,310	10/10/2000	Kurt Haas	1079-2	3443

7590

08/26/2003

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EXAMINER

HAN, MARK K

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,310

Applicant(s)

HAAS ET AL.

Examiner

Mark K Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-15 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 4,784,737 to Ray et al. (hereinafter "Ray").

Ray discloses a device capable of electroporation having singular container 18, conductive fluid 16, a first electrode 22, and a second electrode 26. See Figures 1-4.

In reference to claims 2 and 3, the container is micropipette (col. 4, lines 36-41).

In reference to claim 4, the phrase "glass pulled" is considered a method, which is given no patentable weight in an apparatus claim. Regarding the diameter of the tip, Ray discloses that the tip is inserted into the cell indicating that the diameter of the tip of the micropipette must be less than the diameter of the cell.

In reference to claim 5, the second electrode 26 can be used as a tissue support as disclosed in applicants' specification (p. 8, lines 9-15).

In reference to claims 6 and 7, Ray discloses a periodic pulse power supply 34 (col. 5, lines 61-63).

In reference to claim 8, Ray discloses that the electrodes are made of silver (col. 6, lines 34-35).

In reference to claims 9-14 and 22, Ray discloses the claimed method (col. 6-9).

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In reference to claim 15, Ray uses delivers chromosomes, which are strands of DNA that are made up of nucleic acids, into the cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 15, 16, 18-21, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray in view of U.S. Patent No. 6,245,564 to Goldman et al. (hereinafter "Goldman").

Ray discloses the claimed method as described above but does not show delivering the substances as disclosed in claims 16 and 18-21. Goldman introduces nucleic acid encoding green fluorescent protein (GFP) into a neuron *in vitro* by electroporation. See col. 2, lines 53-60. It would have been obvious to one of ordinary skill in the art to modify the method as disclosed by Ray to deliver nucleic acid encoding GFP to a neuron *in vitro*, as suggested by Goldman, as an obvious engineering alternative.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray in view of U.S. Patent No. 5,789,213 to Hui et al. (hereinafter "Hui").

Ray discloses the claimed method as shown above but does not disclose delivering a fluorochrome dye. Hui uses electroporation to deliver FITC, a fluorochrome (col. 8, lines 19-37). It would have been obvious to one of ordinary skill in the art to modify the method

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disclosed by Ray to deliver a fluorochrome, suggested by Hui, as an obvious engineering alternative.

4. Claims 23-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray in view of U.S. Patent No. 6,233,482 to Hofmann et al. (hereinafter "Hofmann").

Ray discloses the claimed method except for the type of electrical signals and *in vivo* technique. Hofmann shows that various electrical signals can be used in the electroporation of cells *in vivo*. See col. 10, lines 15-30. It would have been obvious to one of ordinary skill in the art to modify the method of Ray to use various electrical signals *in vivo* as suggested by Hofmann for optimum results.

Response to Arguments

5. Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive. In response to applicant's argument that Ray does not teach or disclose either "a singular container having a distal opening for positioning in close proximity to at least one cell" or a device that an electrical signal is capable of passing through the conductive fluid and the cell to allow the substance to pass through the distal opening and enter the cell, the Examiner considers this language as intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.

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See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mkh.

Mark Han
Patent Examiner
Art Unit 3763

mkh
August 25, 2003


MANUEL MENDEZ
PRIMARY EXAMINER